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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,848	07/21/2003	Craig Richard Gerbi	017516-006810US	6559

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PATENT DEPT  
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EXAMINER
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POUS, NATALIE R

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/624,848

Applicant(s)

GERBI ET AL.

Examiner

Natalie Pous

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 February 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18,19,21-31 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) 34-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18,19 and 21-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 18,19,21-31 and 34-39 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/20/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

Newly submitted claims 34-39 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-33, drawn to apparatus, sub-combination, classified in class 606, subclass 108.
- II. Claims 38-39, drawn to apparatus, combination, classified in class 606, subclass 1.
- III. Claims 34-37, drawn to method of use, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

Inventions (I and II) and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the apparatus as claimed may be used in a different process, for instance the apparatus

may be used simply as a guide for an elongate instrument, not necessarily for use with a robotic arm.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the particulars of the sub combination, for instance the engaging formation of the combination is functional language and is not a claimed structural limitation as required by the sub-combination. The subcombination has separate utility such as the sub-combination may be used simply as a guide for an elongate instrument, not necessarily for use with a robotic arm.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in

accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

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unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 34-39 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Response to Arguments***

Applicant's arguments with respect to the claim have been considered but are moot in view of the new ground(s) of rejection in view of Wright.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

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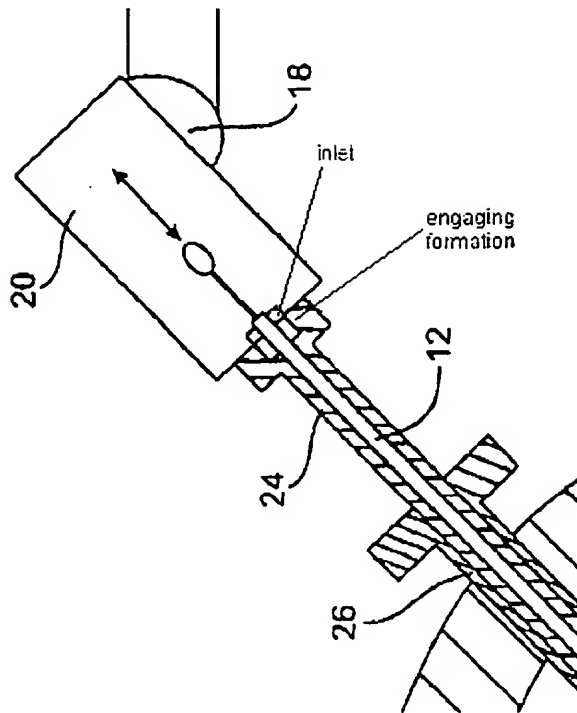
directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 18... rejected under 35 U.S.C. 102(e) as being anticipated by Wright et al. (US 6726699).

Claims 18, 19, 21, 22, 30 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Wright.

Regarding Claim 18, Wright teaches a tool guide comprising: an elongate body (24) defining opposed ends and a passage extending within the body between opposed ends (fig. 1); and an engaging formation defined within the passage of the body (see fig below), the engaging formation being capable of holding and providing a stop for a complementary engaging formation on a robotic arm so that a passage defined within the complementary engaging formation is aligned with the passage of the elongate body



and a surgical instrument passing through may be guided to a surgical site in a patient body when the elongate body is inserted through an aperture of the patient body (fig. 1, it is noted that all language after the word "for" in line 5 is functional language and not positively claimed, thus the prior art must simply be capable of performing the function set forth, based on structural limitations of the claims. The device of Wright meets the structural claim limitations, and is thus capable of performing the functions set forth in the claim)

Regarding Claim 19, Wright teaches the tool guide of claim 18, wherein the engaging formation comprises a socket formation (see figure above)

Regarding Claim 21, Wright teaches the tool guide of claim 19, which comprises an inlet (see figure above) which leads into passage, the inlet being arranged to be accessible from outside the patient body (fig. 1) when the tool guide is mounted in the



aperture, the socket formation being positioned adjacent the inlet, and an outlet (44) which leads from the passage, the outlet being arranged to be positioned within the patient body (14) when the tool guide is mounted on the patient body (fig. 1).

Regarding Claim 30, Wright teaches a tool guide of claim 18, which comprises a cross-sectionally circular tubular portion defining the outlet (32).

Regarding Claim 31, Wright teaches the tool guide of claim 30, in which all of the cross-sectionally circular tubular portion tapers radially outwardly in a rearward direction away from the outlet (44).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wright in view of Bonutti et al. (US 5320611). Wright teaches all limitations of preceding dependent claims 18, 19 and 21 as previously described, and further teaches wherein

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the socket formation comprises a circumferentially extending surface defining at least part of the passage (see fig above), but fails to teach wherein the surface tapers radially inwardly in a direction away from the inlet. Bonutti teaches a device for guiding a surgical instrument into the body, wherein the device comprises a socket formation with a circumferentially extending surface defining at least part of the passage and wherein the surface tapers radially inwardly in a direction away from the inlet in order to guide an instrument into the passage. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Wright with a tapered surface in order for the surface to act as a guide.

Claims 23 and 24 rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Wright and Bonutti, and further in view of Ciccolella et al. (US 6224608).

The combination of Wright and Bonutti teaches all limitations of preceding dependent claims 18, 19, 21 and 22 as previously described, but does not teach wherein the outer surface defines at least one gripping formation and wherein the gripping formation comprises a rib extending helically around the outer surface. Ciccolella teaches a tissue holding device wherein the outer surface comprises a gripping formation comprising a helically extending rib (12) in order to maintain the desired positional relationship between the tool guide and the body tissue. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Wright and Bonutti with a gripping formation comprising a

helically extending rib in order to maintain the desired positional relationship between the tool guide and the body tissue.

Claims 23 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Wright and Bonutti in view of Honkanen et al. (US 4655752).

The combination of Wright and Bonutti teaches all limitations of preceding dependent claims 18, 19 and 21 as previously described, but does not teach the following

Wherein the outer surface comprises at least one gripping surface

Wherein the gripping formation comprises a plurality of ribs

A sealing formation covering the inlet

The sealing formation formed from a synthetic plastic

The sealing formation formed of silicone

The elongate body is at least partially made of steel

Regarding the gripping formation limitations, Honkanen teaches a surgical cannula comprising a plurality of rib formations (35) disposed on the surface of the cannula (40) in order to enhance the ability of the cannula to remain in place and make a tight seal with the surrounding tissue, without causing excess trauma to the tissue (Column 2, proximate lines 27-31). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Wright and Bonutti with the rib formations of Honkanen in order to enhance the ability of the cannula to remain in place and make a tight seal with the surrounding tissue, without causing excess trauma to the tissue.

Regarding the seal formation limitations, Honkanen teaches a surgical cannula comprising a plastic, such as silicone (Column 3, proximate lines 45-55) seal formation (70) in order to seal against annoying fluid backflow both when an instrument is inserted in the cannula and when one is not (column 2, proximate lines 9-14). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Wright and Bonutti with a silicone seal as taught by Honkanen in order to seal against annoying fluid backflow both when an instrument is inserted in the cannula and when one is not.

Regarding the limitation wherein the elongate body is at least partially made of steel, Honkanen teaches wherein the cannula may be lined with metal near the bottom end of the cannula for use as a drilling device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Wright and Bonutti with a portion of the cannula made of metal such as steel in order to use the device as a drilling device.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP  
4/2/07

  
ANH TUAN T. NGUYEN  
SUPERVISORY PATENT EXAMINER

4/2/07